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Revised Recommendations for HIV Testing in Healthcare Settings

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Acknowledgements

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Presentation Outline

- ***WHAT?***
  - CDC's New Recommendations
- ***WHY?***
  - The case for increased HIV testing
- ***HOW?***
  - Challenges to implementation

Revised Recommendations Adults & Adolescents

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- Repeat HIV screening of persons with known risk at least annually

Revised Recommendations Adults & Adolescents

- Opt-out HIV screening with the opportunity to ask questions and the option to decline
- Include HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling in conjunctions with HIV screening in health care settings is not required

Revised Recommendations Adults & Adolescents

- Intended for all health care settings, including inpatient services, EDs, urgent care clinics, STD clinics, TB clinics, public health clinics, community clinics, substance abuse treatment centers, correctional health facilities, primary care settings

Revised Recommendations Adults & Adolescents

- Communicate test results in same manner as other diagnostic/screening tests
- Provide clinical HIV care or establish reliable referral to qualified providers

Revised Recommendations Adults & Adolescents

- Low prevalence settings:
  - Initiate screening
  - If yield from screening is less than 1 per 1000, continued screening is not warranted
- Steps must be taken to resolve conflicts between the recommendations and state or local regulations

Revised Recommendations Pregnant Women

- Universal opt-out HIV screening
  - Include HIV in routine panel of prenatal screening tests
  - Consent for prenatal care includes HIV testing
  - Notification and option to decline

Revised Recommendations Pregnant Women

- Second test in 3rd trimester for pregnant women:
  - Known to be at risk for HIV
  - In jurisdictions with elevated HIV incidence
  - In high HIV prevalence health care facilities

Revised Recommendations Pregnant Women

- Opt-out rapid testing with option to decline for women with undocumented HIV status in L&D
  - Initiate ARV prophylaxis on basis of rapid test result
- Rapid testing of newborn recommended if mother's status unknown at delivery
  - Initiate ARV prophylaxis within 12 hours of birth on basis of rapid test result

Terminology

- ***Diagnostic testing:*** performing an HIV test based on clinical signs or symptoms
- ***Screening:*** performing an HIV test for all persons in a defined population

Terminology

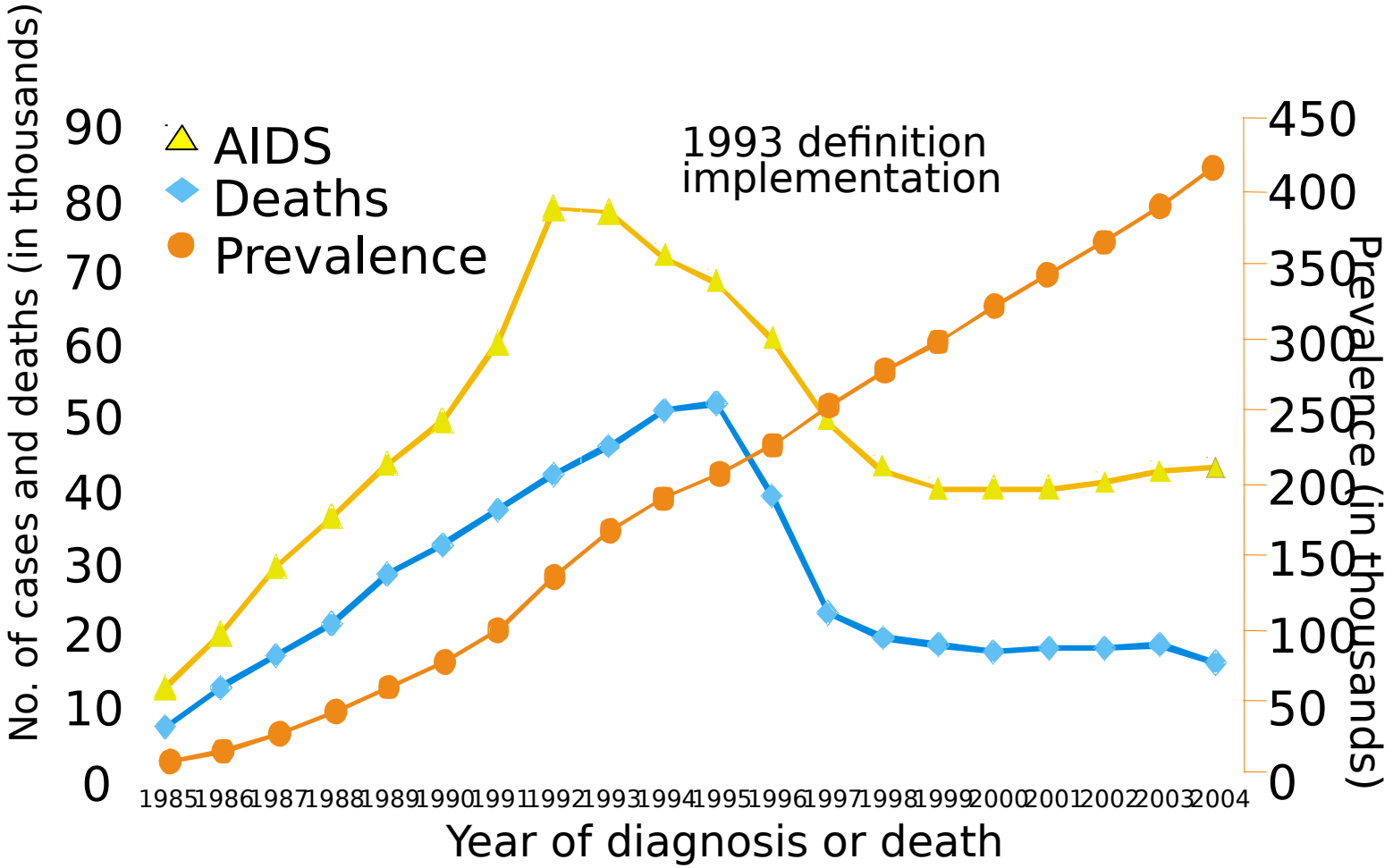
- ***Targeted testing****:* performing an HIV test on subpopulations of persons at higher risk based on behavioral, clinical or demographic characteristics
- ***Opt-out screening****:* performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines

Why the change?

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk

- Repeat HIV screening of persons with known risk at least annually

Estimated Number of AIDS Cases, Deaths, and Persons Living with AIDS,1985-2004, United States



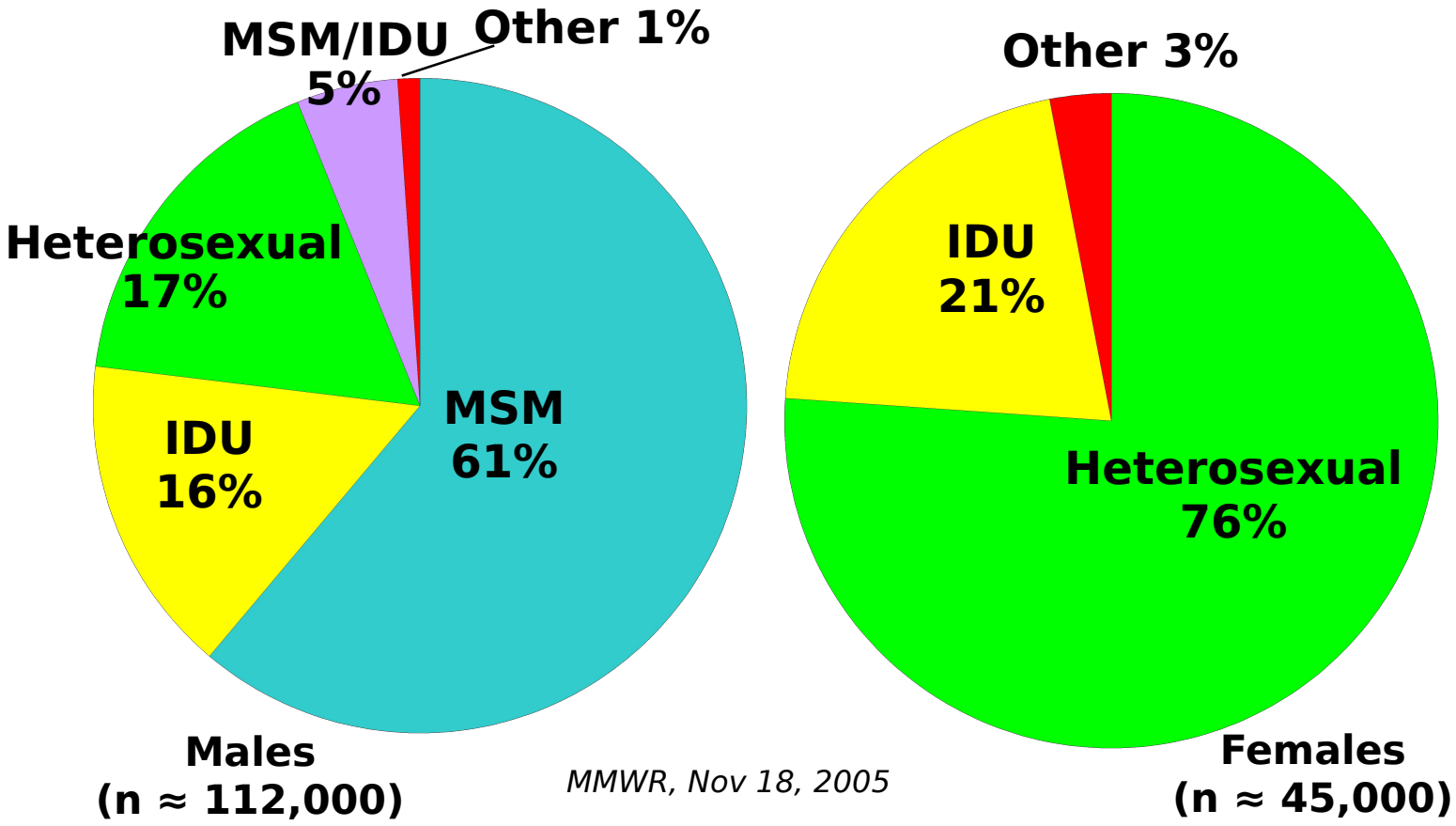
Note. Data adjusted for reporting delays.

Awareness of HIV Status among Persons with HIV, United States

Number HIV infected	1,039,000 – 1,185,000
Number unaware of their HIV infection	252,000 - 312,000 (24%-27%)
Estimated new infections annually	40,000

Glynn M, Rhodes P. 2005 HIV Prevention Conference

HIV/AIDS Diagnoses among Adults and Adolescents, by Transmission Category — 33 States, 2001–2004



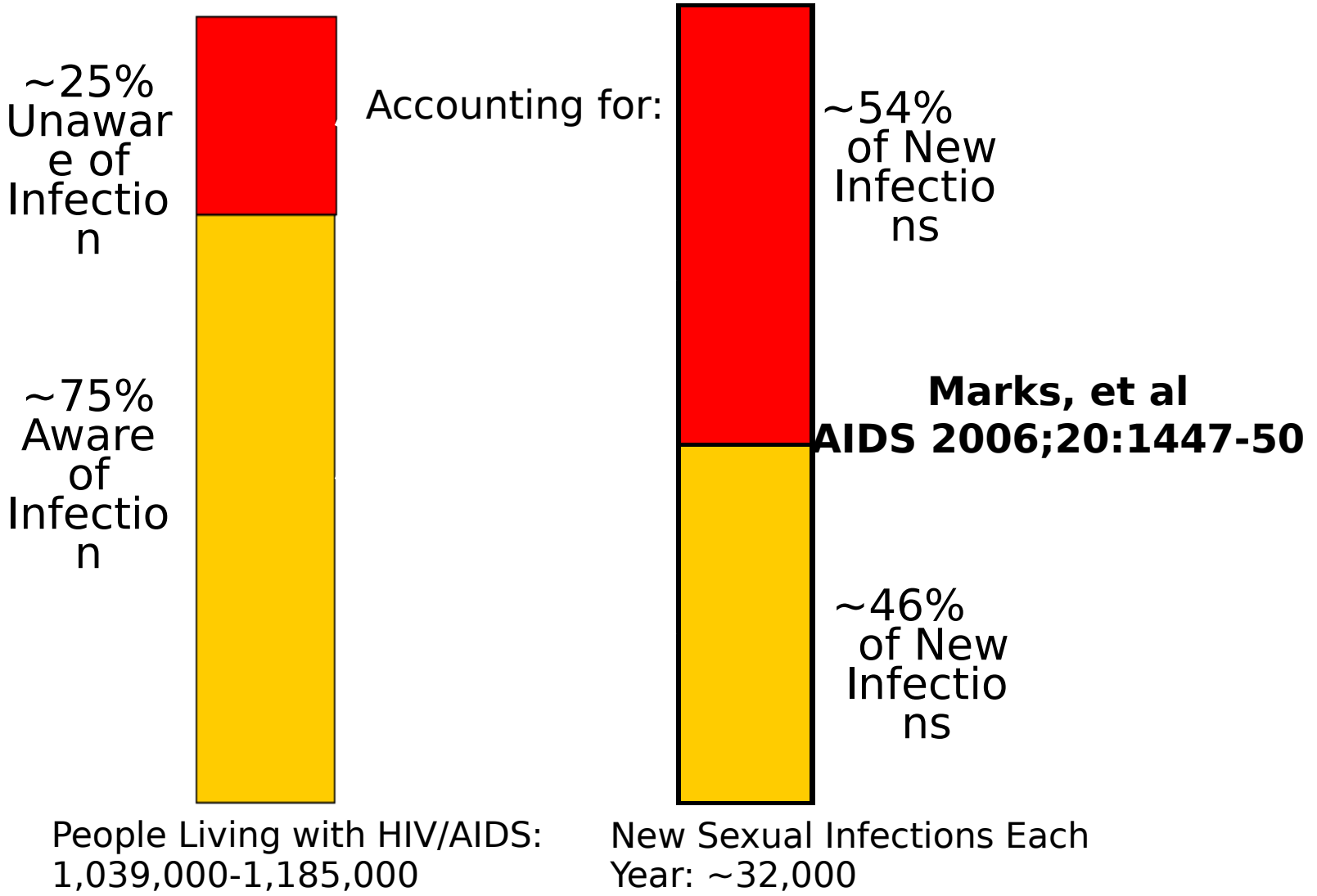
MMWR, Nov 18, 2005

Awareness of HIV Status Correlates with HIV Transmission Rate

- HIV-positive and unaware of status
  - Estimated transmission rate 8.8-10.8%
- HIV positive and aware of status
  - Estimated transmission rate 1.7-2.4%

Holtgrave D. et al *Int J STD AIDS*. 2004; 15: 789
Marks G et al. *JAIDS.* 2005; 39:446.

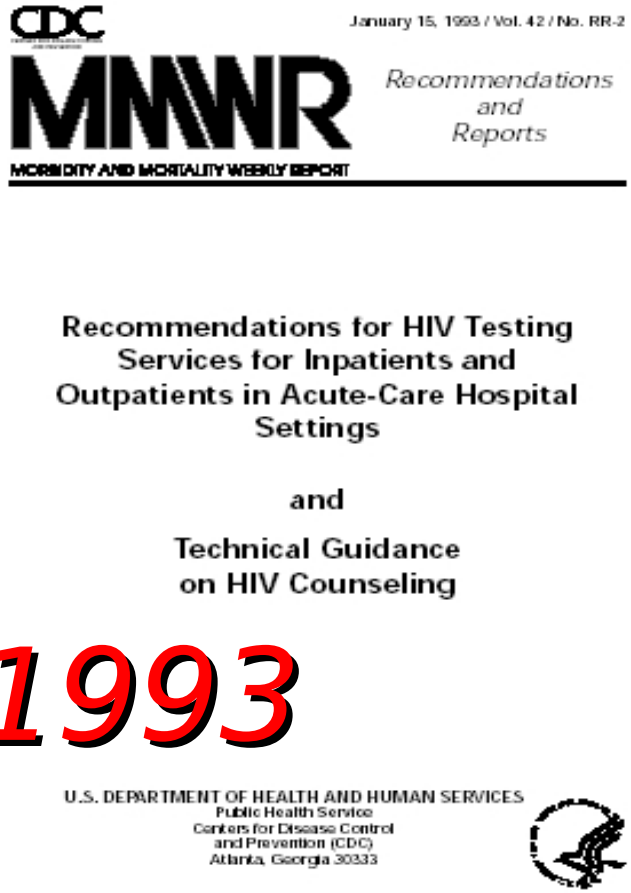
Awareness of Serostatus Among People with HIV and Estimates of Transmission



Previous Guidelines and their Effects:

Who is being tested?
Where are tests being done?

Previous Recommendations



CDC

January 15, 1993 / Vol. 42 / No. RR-2

MMWR

Recommendations and Reports

MORBIDITY AND MORTALITY WEEKLY REPORT

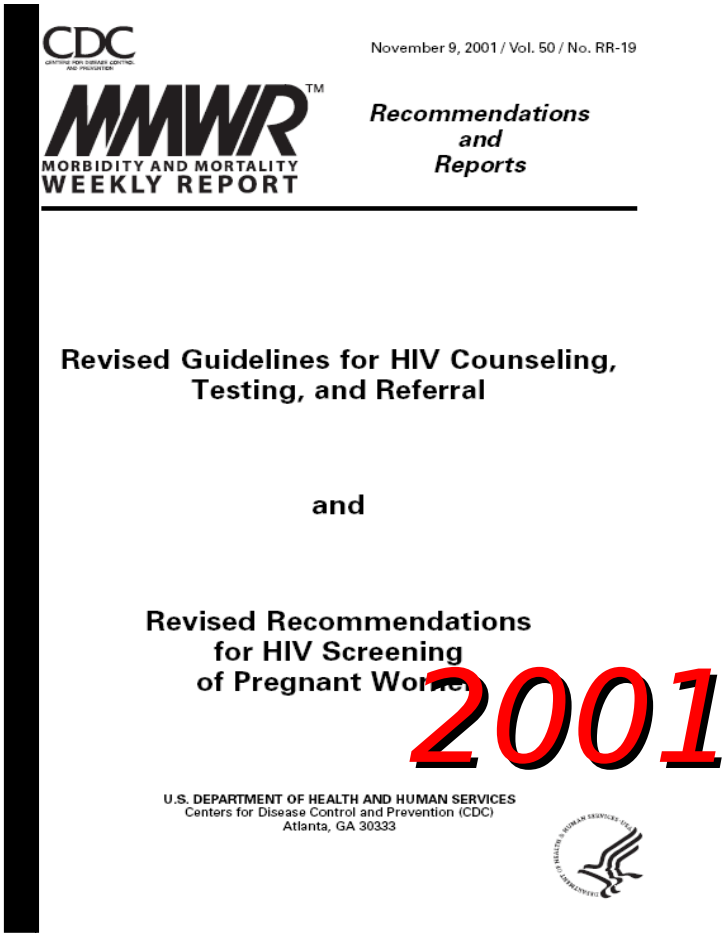
Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings

and

Technical Guidance on HIV Counseling

1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia 30333



CDC

November 9, 2001 / Vol. 50 / No. RR-19

MMWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

Recommendations and Reports

Revised Guidelines for HIV Counseling, Testing, and Referral

and

Revised Recommendations for HIV Screening of Pregnant Wo

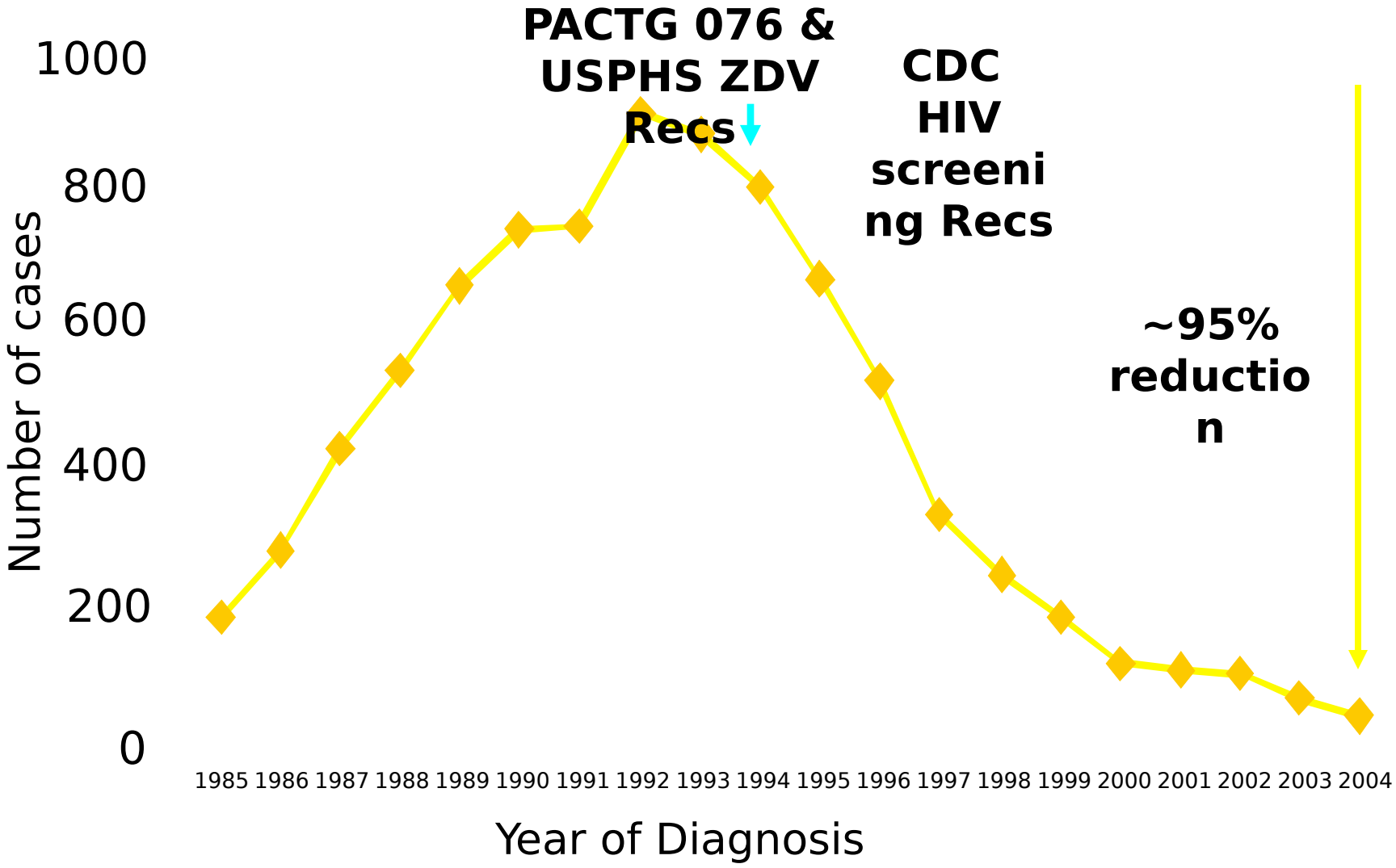
2001

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

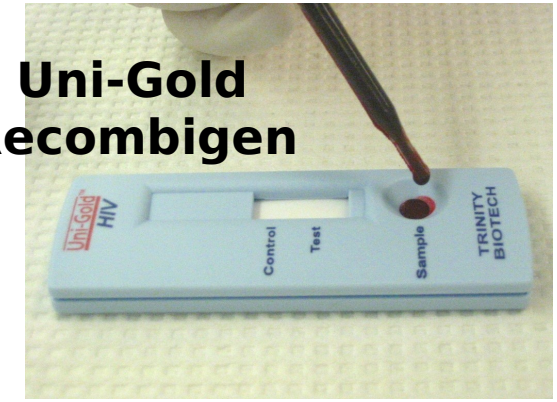
Previous CDC Recommendations Pregnant Women: A Real Success Story

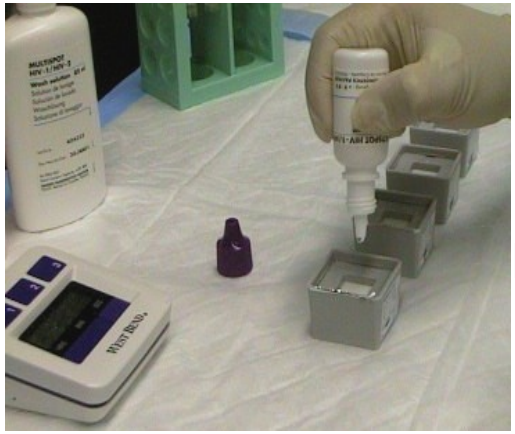
- Routine, voluntary HIV testing as a part of prenatal care, as early as possible, for all pregnant women
- Simplified pretest counseling
- Flexible consent process

Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2004 – United States

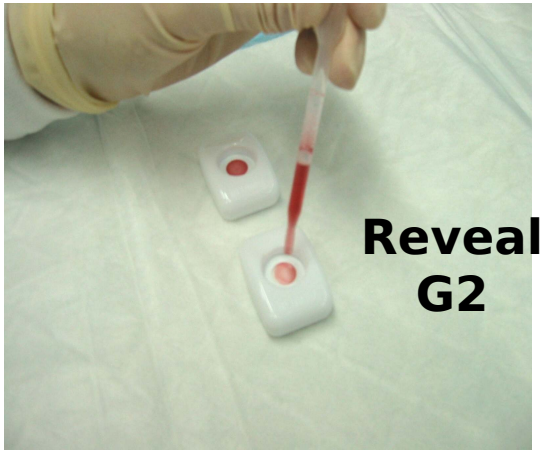


Uni-Gold
Recombigen



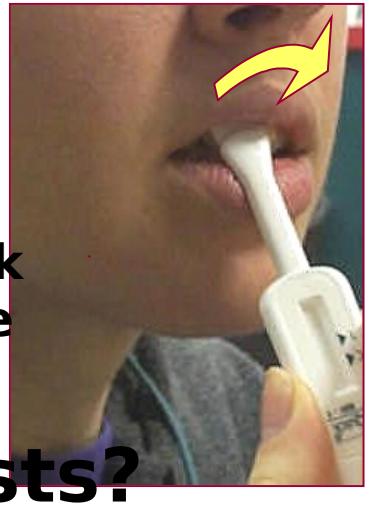


Multispot
HIV-1/HIV-
2



Reveal
G2

OraQuick
Advance



How good are rapid tests?

HIV Screening with OraQuick in MIRIAD
Mother Infant Rapid Intervention At Delivery

Testing of pregnant women in labor for whom no HIV test results are available; 12 hospitals in 5 cities

7680 women screened

- 54 (0.7%) new HIV infections identified
- 6 false positive OraQuick tests, no false negatives
- 15 false-positive EIAs

Specificity: OraQuick 99.92%; EIA 99.80%

Positive predictive value: OraQuick 90%; EIA 76%

Bulterys et al, JAMA July 2004

Previous CDC Recommendations Adults & Adolescents

- Routinely recommend HIV screening in settings with *high HIV prevalence (≥1%)*
- *Targeted testing based on risk assessment*
- Routinely recommend HIV Testing seeking treatment for STDs
- Annual testing for sexually active MSM

Are Recommendations Having Their Intended Effect?

Recommendations Are Not Having Their Intended Effect in Acute Care Settings

- **EDs account for 10% of all ambulatory care visits**

	2000	2001	2002
ED visits	108 million	107 million	110 million
Age 15-64	68.3 million	69.4 million	69.6 million
HIV serology	215,000	201,000	163,000

Characteristics, Rapid Test Positive Patients Identified in ED Screening

	N= 83
No previous test	47 (57%)
Risk factors	
MSM	30 (34%)
IDU	8 (10%)
High risk hetero partner	3 (4%)
No identified risk	42 (51%)

- *Cook County Bureau of Health Services, 2003*

HIV Testing Practices in EDs

- Survey of 154 ED providers
  - Average: 13 STD patients per week
  - Only 10% always recommend HIV test
- Reasons for not testing for HIV:
  - 51% concerned about follow up
  - *45% not a “certified” counselor*
  - *19% too time-consuming*
  - 27% HIV testing not available

-Fincher-Mergi et al, 2002: AIDS Pat Care STDs

HIV Testing Practices in EDs

- Survey of 95 Academic EDs
- For patients with suspected STDs:
  - 93% screen for gonorrhea
  - 88% screen for chlamydia
  - 58% screen for syphilis
  - 3% screen for HIV

- Wilson et al, 1999: Am J Emerg Med

HIV Prevalence and Proportion of Unrecognized HIV Infection Among 1,767 MSM, by Age Group and Race/Ethnicity NHBS, Baltimore, LA, Miami, NYC, San Francisco

	Total Tested	HIV Prevalence		Unrecognized HIV Infection	
Age Group (yrs)		**No.**	**%**	**No.**	**%**
18-24	410	57	(14)	45	(79)
25-29	303	53	(17)	37	(70)
30-39	585	171	(29)	83	(49)
40-49	367	137	(37)	41	(30)
≥ 50	102	32	(31)	11	(34)
Race/Ethnicity					
White	616	127	(21)	23	(18)
Black	444	206	(46)	139	(67)
Hispanic	466	80	(17)	38	(48)
Multiracial	86	16	(19)	8	(50)
Other	139	18	(13)	9	(50)
Total	**1,767**	**450**	**(25)**	**217**	**(48)**

MMWR June 24, 2005

Source of HIV Tests & Positive Tests

- **38% - 44% of adults age 18-64 have been tested**
- **16-22 million persons age 18-64 tested annually in U.S.**

	HIV tests*	HIV+ tests**
Private doctor/HMO	**44%**	**17%**
Hospital, ED, Outpatient	**22%**	**27%**
Community clinic (public)	**9%**	**21%**
HIV counseling/testing	**5%**	**9%**
Correctional facility	**0.6%**	**5%**
STD clinic	**0.1%**	**6%**
Drug treatment clinic	**0.7%**	**2%**

National Health Interview Survey, 2002
****Suppl. to HIV/AIDS surveillance, 2000-2003***

Late HIV Testing is Common

- **Among 4,127 persons with AIDS***
  - 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis (“late testers”)

MMWR, June 27, 2003; Hanna et al, CROI 2006 Abstract 925

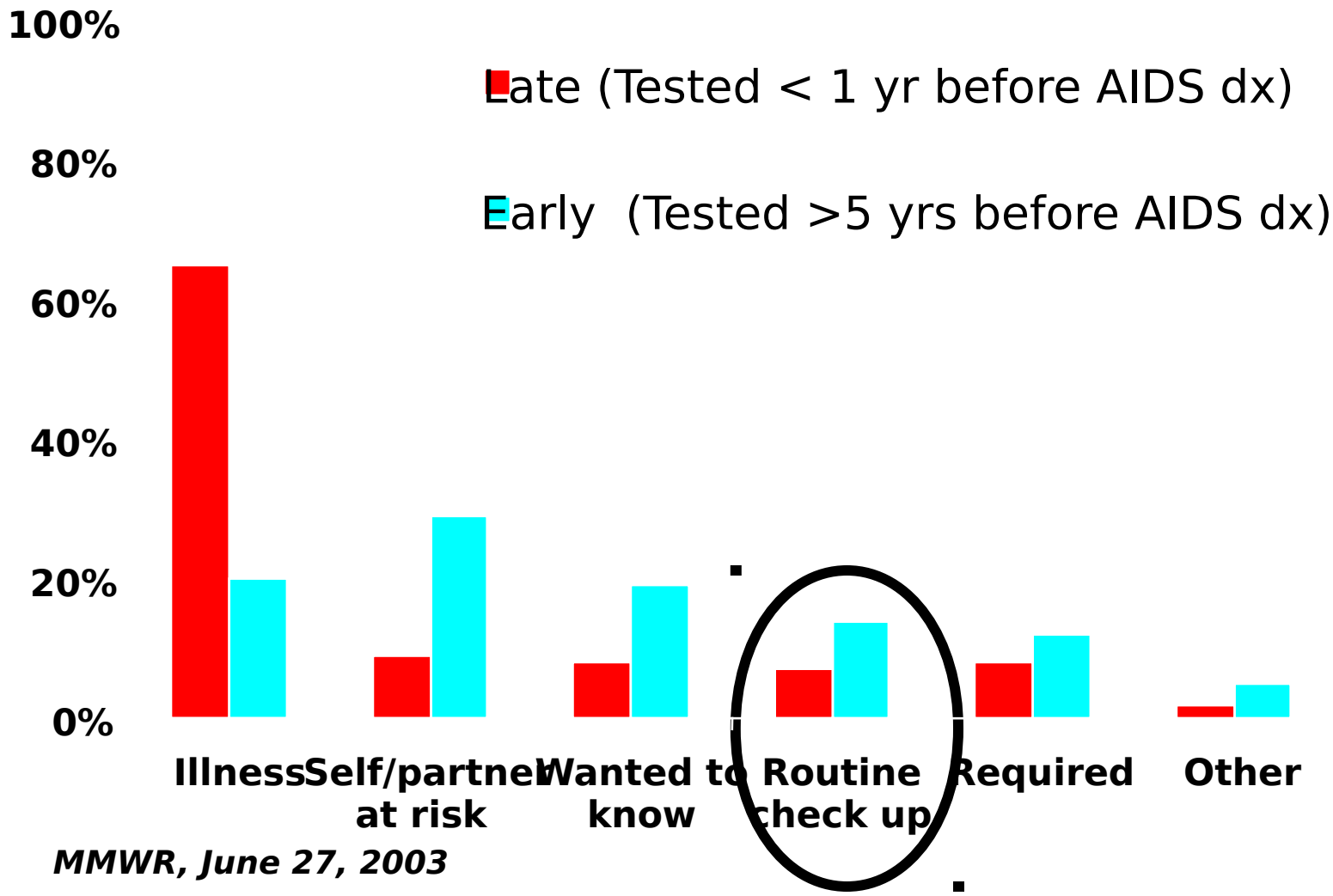
Late HIV Testing is Common

- **Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:**
  - Younger (18-29 yrs)
  - Heterosexual
  - Less educated
  - African American or Hispanic
  - Dead within less than one year of AIDS diagnosis

MMWR, June 27, 2003; Hanna et al, CROI 2006 Abstract 925

Reasons for testing: late versus early testers

Supplement to HIV/AIDS Surveillance, 2000-2003



MMWR, June 27, 2003

Missed Opportunities

- **Review of 4515 HIV cases in S. Carolina, 2001-2005**
  - 41% found to be HIV positive within 1 year of AIDS diagnosis

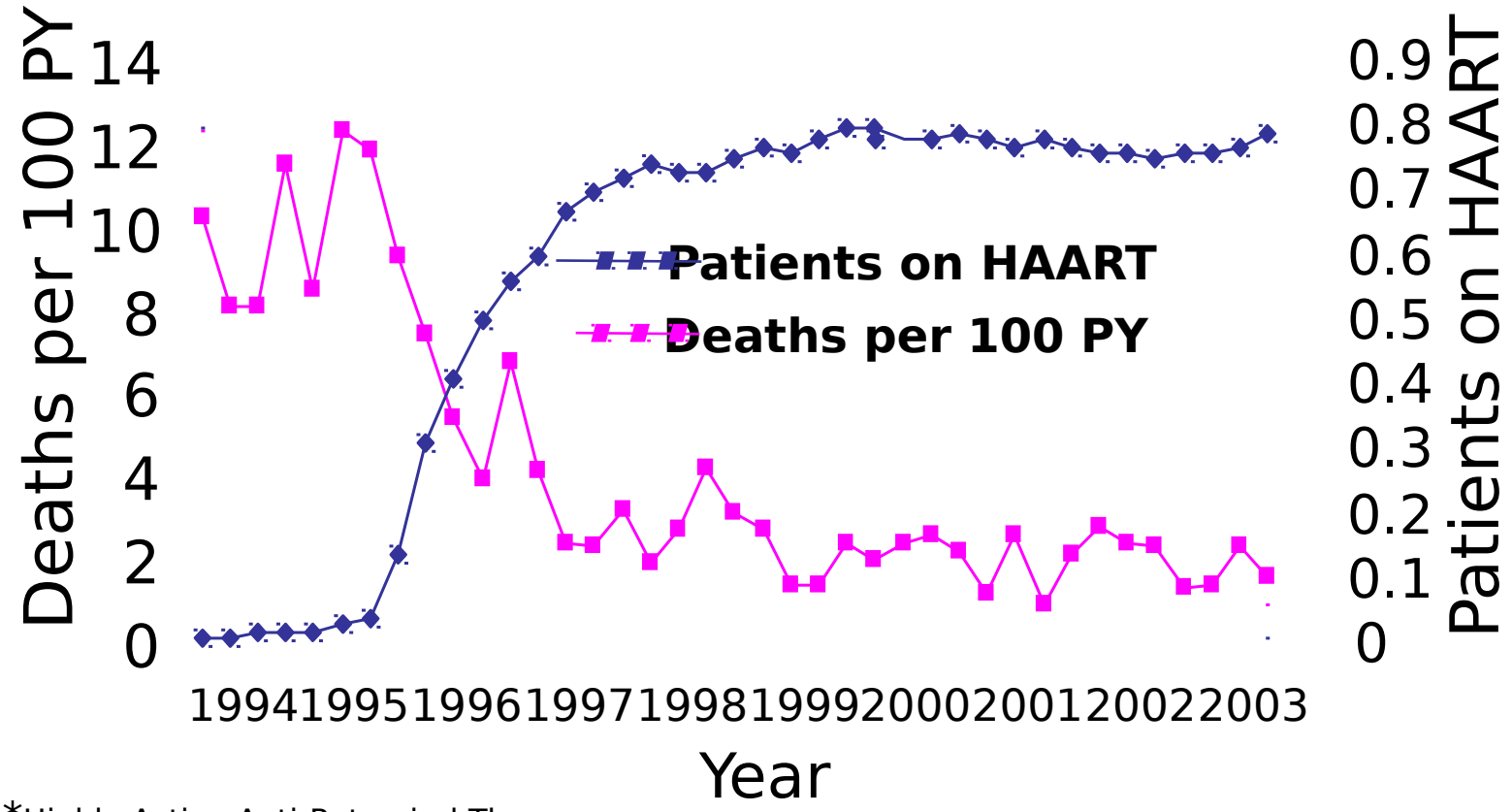
CDC: MMWR Weekly, Dec. 1, 2006; 55(47):1269

Missed Opportunities

- **Analysis of 1302 “late testers”**
  - Total number of health care visits without HIV testing: 7988
  - Average number of contacts before testing: 4
    - Risk based visits: 1711
    - No risk at visit: 6277

CDC: MMWR Weekly, Dec. 1, 2006; 55(47):1269

Mortality & HAART* Use Over Time HIV Outpatient Study, CDC, 1994-2003



*Highly Active Anti-Retroviral Therapy

Knowledge of HIV Infection & Behavior

After people become aware they are HIV-positive, the prevalence of high-risk sexual behavior is reduced substantially

Reduction in Unprotected Anal or Vaginal Intercourse with HIV-neg partners:

HIV-pos Aware vs. HIV-pos Unaware **68 %**

Knowledge of HIV Infection & Behavior

Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the U.S.

Marks G, et al. JAIDS. 05;39:446

Why the change?

- Opt-out HIV screening with the opportunity to ask questions & the option to decline

Opt-Out Screening

Prenatal HIV testing for pregnant women:

- 4 counseling models with opt-in consent:
  - *35% accepted testing*
  - *Some women felt accepting an HIV test indicated high risk behavior*

Simpson W, et al, BMJ June,1999

Opt-Out Screening

- Testing offered as routine, opportunity to decline
  - *88% accepted testing*
  - *Significantly less anxious about testing*

Simpson W, et al, BMJ June,1999

Routine Opt-Out HIV Testing
Texas STD Clinics, 1996-97

	Opt-In N (%)	Opt-Out N (%)	% change
STD Visits	**31,558**	**34,533**	**+9**
Eligible Clients	**19,184 (61)**	**23,686 (69)**	**+23**
Pre-test counsel	**15,038 (78)**	**11,466 (48)**	**-24**
Tested	***14,927 (78)***	***23,020 (97)***	***+54***
Post-test counsel	**6,014 (40)**	**4,406 (19)**	**-27**
HIV-positive	***168 (1.1)***	***268 (1.2)***	***+59***

Texas Department of State Health Services, 2005

Why the change?

- Include HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling in conjunctions with HIV screening in health care settings is not required

Lessons Learned

Barriers among Health Care Providers

- Difficult to obtain written consent & provide counseling, yet still screen the large numbers of patients in acute care settings
- Sustainability will depend on additional staff, streamlined systems, or both

Lessons Learned

Barriers among Health Care Consumers

- Stigma
- Shame
- Fear
- Denial

Effect of Counseling in Conjunction with HIV Testing: Does It Make a Difference?

- Meta-analysis of 27 studies of HIV-CT:
  - ***HIV-positive*** **participants reduced unprotected intercourse and increased condom use.**
  - ***HIV-negative*** **participants did not modify their behavior more than untested participants.**

- Weinhardt et al, 1999: Am J Public Health

Is Routine HIV Testing Cost Effective?

- Expanded screening for HIV in the U.S. – an analysis of cost effectiveness

Paltiel AD, et al. NEJM 2005;352:586

Is Routine HIV Testing Cost Effective?

- “In all but the lowest-risk populations, routine, voluntary screening for HIV once every 3 to 5 years is justified on both clinical and cost-effectiveness grounds. One-time screening in the general population may also be cost-effective.”

Paltiel AD, et al. NEJM 2005;352:586

Rationale for Rapid HIV Tests

- High rates of non-return for test results
  - In 2000, 31% did not return for results of HIV-positive conventional tests at publicly funded sites
- Need for immediate information or referral for treatment choices
  - Perinatal settings
  - Post-exposure treatment settings
- Screening in high-volume, high-prevalence settings

Rapid Testing: Confirmation & Follow-up

- Confirmatory test is essential, usually Western Blot

- Follow-up testing of persons with negative or indeterminate Western blot results after 4 weeks

Role for Rapid HIV Tests

- Increase receipt of test results
- Increase identification of HIV-infected pregnant women so they can receive effective prophylaxis
- Increase feasibility of testing in acute-care settings with same-day results
- Increase number of venues where testing can be offered to high-risk persons

Summarizing Rationale for Revised Recommendations

- Many HIV-infected persons access health care but are not tested for HIV until symptomatic
- Effective treatment available
- Awareness of HIV infection leads to substantial reductions in high-risk sexual behavior

Summarizing Rationale for Revised Recommendations

- Inconclusive evidence about prevention benefits from typical counseling for persons who test negative
- Great deal of experience with HIV testing, including rapid tests

Challenges to Implementation

- State laws
  - Currently requires special consent, pre- and post-test counseling
- Special populations
  - Adolescents, non-English speaking persons, inmates, mentally ill
- Unintended consequences
  - Domestic violence, job & housing discrimination, mental health issues

Challenges to Implementation

- Organizational issues
  - Administrative buy-in
  - Agency policies and procedures
  - Reimbursement
  - Limited personnel, staff time
  - Unsure of skills in discussing sensitive issues

Assess, ***C***onsent, ***T***est, ***S***upport

- Four-step process designed to make provider-delivered HIV testing feasible in clinical setting
  - Provides instruction and tools for making operational and clinical practice changes
  - Condenses 45-minute process to 5-10 minutes

*A*ssess

- Explain it is now standard practice to discuss HIV with all patients.
  - Include how HIV is transmitted and benefits of testing.
- Review risk screen.
  - Testing is particularly important for those with substance abuse or sexual risk factors.
- Assess testing readiness.
  - For rapid testing, be sure to assess if they are ready to get results during their visit.

*A*ssess

- “I discuss routine HIV testing with all my patients. I’d like to tell you the benefits of getting an HIV test.”

- “I’d also like to make sure you know how the virus is transmitted. What do you know about HIV transmission?”

- “You might want to consider getting an HIV test today. It will only take a few minutes and we can discuss safer sex methods following the test.”

- “Do you have any questions or concerns?”

Consent

- Review the consent form:
  - Meaning of positive and negative results
  - Confidential vs. anonymous testing
  - Partner notification
  - Domestic violence screening
- Obtain consent
  - Consent form should provide only necessary information.
- Pre-test counseling required but can be expedited by written materials.

Consent

- “You are required to fill out this consent form for your HIV test.”

- “Should you test positive, your name will be given to the health department. This is a confidential process. You will also be given information about counseling and treatment. We will also discuss partner notification which is a completely voluntary process as well.”

- “We also need to talk about things you can do to prevent the spread of HIV and your exposure to HIV and other STDs.”

Test

- Describe/provide the HIV test:
  - Blood
  - Oral
  - Urine
  - Rapid
- Establish a plan to deliver results or have patient wait for rapid test results:
  - ***“We’ll contact you when the results are available. It should take about a week.”***

*S*upport

- Give results and allow time to process
  - HIV-Negative
    - Clarify if need to retest in 3 months
    - Discuss prevention
- Use written materials to supplement post-test counseling.

Support

- Give results and allow time to process
  - HIV-Positive
    - Provide support and link to care
    - Review HIV reporting, partner notification, and domestic violence issues
- Use written materials to supplement post-test counseling.

Support : Negative Results

- “Your test for HIV came back negative”
- “Have you had unprotected sex or been involved in an at-risk behavior in the past 6 months?”
  - Explain the window period and suggest repeat test in 3 months
- “Here are some things you might consider to reduce your risk of infection in the future…”

*S*upport: Positive Results

- “Your test for HIV was positive
- This means you have the HIV virus but not necessarily that you have AIDS
- There are many treatments available that can help you live a long and healthy life, even with HIV infection”

NOTE: A positive test result is from a confirmatory test, not a rapid test or screening test. A patient should never be told he or she is positive based on the results of a rapid test.

Support: Positive Results

- Answer questions and concerns, discuss support services they can access:
  - "I will refer you to the following treatment center for additional support and care."
  - "We should also discuss methods you can adopt to prevent the spread of the virus…"

Support: Positive Results

- Partner notification
  - "You have the choice to notify your partner. You may choose to tell him/her, we can assist with notification, or the health department can notify your partner(s) anonymously."

Domestic Violence Risk

- **What response would you anticipate from your partner if he/she were notified of a possible exposure to HIV?**
  - Have you ever felt afraid of your partner?
  - Has your partner ever pushed, grabbed, slapped, choked or kicked you?

Domestic Violence Risk

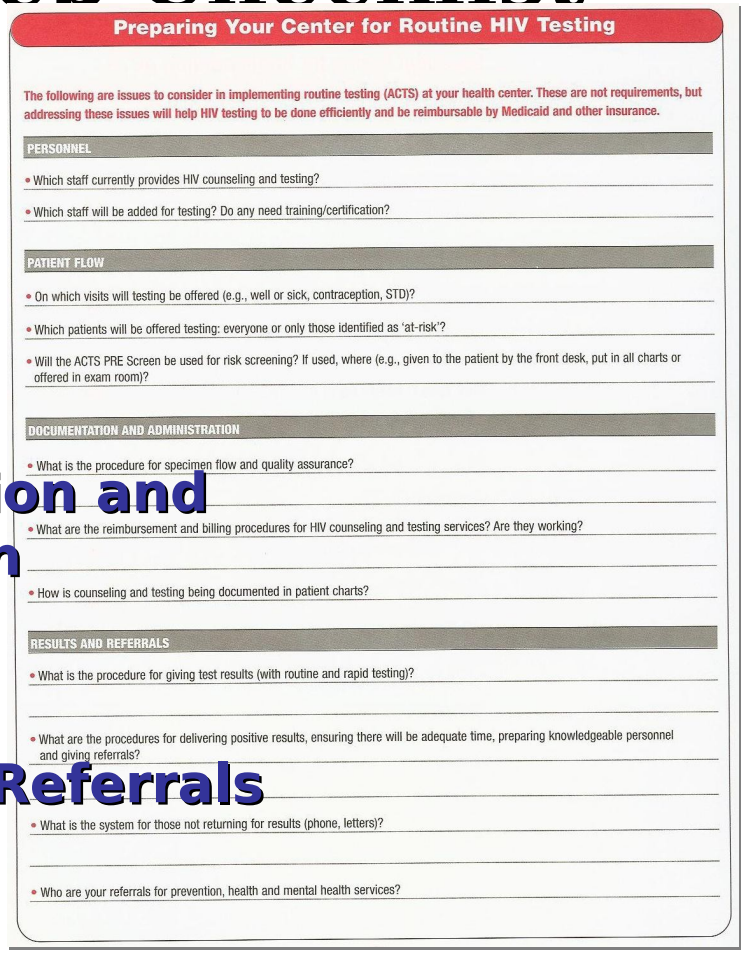
- Has your partner ever threatened your children, family members or someone close to you?
- Do you think that notification of this partner will have a severe negative effect on your physical health and safety or that of your children or someone close to you?

Challenges to Implementation

- Who will pay for testing?
- Who will pay for treatment?
- How will increased case load be handled?
- How will patients who fail to follow up for test results be contacted?

ACTS Site Prep Checklist

- Personnel
- Patient Flow
- Documentation and Administration
- Results and Referrals



Preparing Your Center for Routine HIV Testing

The following are issues to consider in implementing routine testing (ACTS) at your health center. These are not requirements, but addressing these issues will help HIV testing to be done efficiently and be reimbursable by Medicaid and other insurance.

PERSONNEL

- Which staff currently provides HIV counseling and testing?
- Which staff will be added for testing? Do any need training/certification?

PATIENT FLOW

- On which visits will testing be offered (e.g., well or sick, contraception, STD)?
- Which patients will be offered testing: everyone or only those identified as 'at-risk'?
- Will the ACTS PRE Screen be used for risk screening? If used, where (e.g., given to the patient by the front desk, put in all charts or offered in exam room)?

DOCUMENTATION AND ADMINISTRATION

- What is the procedure for specimen flow and quality assurance?
- What are the reimbursement and billing procedures for HIV counseling and testing services? Are they working?
- How is counseling and testing being documented in patient charts?

RESULTS AND REFERRALS

- What is the procedure for giving test results (with routine and rapid testing)?
- What are the procedures for delivering positive results, ensuring there will be adequate time, preparing knowledgeable personnel and giving referrals?
- What is the system for those not returning for results (phone, letters)?
- Who are your referrals for prevention, health and mental health services?

Resources

- CDC Recommendations

  www.cdc.gov/hiv/topics/testing/index.htm

  www.adolescentaids.org

- State Laws on Testing

  www.ucsf.edu/hivcntr/

- AETC National Resource Center

  www.aidsetc.org

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